



Agricultural Marketing Service

7 CFR Part 205

[Document Number AMS-NOP-19-0102; NOP-19-05]

RIN 0581-AD93

National Organic Program; National List of Allowed and Prohibited Substances - Crops and Handling from October 2019 NOSB

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the National List of Allowed and Prohibited Substances (National List) section of the United States Department of Agriculture's (USDA's) organic regulations to add potassium hypochlorite for pre-harvest use as a sanitizer in organic crop production and fatty alcohols for sucker control in organic tobacco production. In addition, this rule proposes to remove the listing for dairy cultures, as it is redundant with an existing listing.

DATES: Comments must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Interested persons may comment on the proposed rule using the following procedures:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: Jared Clark, Standards Division, National Organic Program, USDA-AMS-NOP, 1400 Independence Ave. SW, Room 2642-S, Ag Stop 0268, Washington, DC 20250-0268. Telephone: (202) 720-3252.

Instructions: All submissions received must include the docket number AMS-NOP-19-0102, NOP-19-05, and/or Regulatory Information Number (RIN) 0581-AD93 for this

rulemaking. When submitting a comment, clearly indicate the proposed rule topic and section number to which the comment refers. In addition, comments should clearly indicate whether the commenter supports the action being proposed and clearly indicate the reason(s) for the position. Comments can also include information on alternative management practices, where applicable, that support alternatives to the proposed amendments. Comments should also offer any recommended language change(s) that would be appropriate to the position. Please include relevant information and data to support the position such as scientific, environmental, manufacturing, industry, or impact information, or similar sources. Only relevant material supporting the position should be submitted. All comments received will be posted without change to <https://www.regulations.gov>.

Document: To access the document and read background documents, or comments received, go to <https://www.regulations.gov> (search for Docket ID AMS-NOP-19-0102).

FOR FURTHER INFORMATION CONTACT: Jared Clark, Standards Division, National Organic Program. Telephone: (202) 720-3252.

SUPPLEMENTARY INFORMATION:

I. Background

On December 21, 2000, the Secretary established the National List within part 205 of the USDA organic regulations (7 CFR 205.600 through 205.607). The National List identifies the synthetic substances allowed in organic farming and the nonsynthetic substances prohibited in organic farming. The National List also identifies nonagricultural and nonorganic agricultural substances (ingredients) that may be used in organic handling.

The Organic Foods Production Act of 1990 (OFPA), as amended (7 U.S.C. 6501–6524), and the USDA organic regulations (7 CFR Part 205) specifically prohibit the use of any synthetic substance in organic production and handling unless the synthetic

substance is on the National List (§§ 205.601, 205.603 and 205.605(b)). Section 205.105 also requires that any nonorganic agricultural substance and any nonsynthetic nonagricultural substance used in organic handling be on the National List (§§ 205.605(a) and 205.606). Under the authority of OFPA, the National List can be amended by the Secretary based on recommendations presented by the National Organic Standards Board (NOSB). Since the final rule establishing the National Organic Program (NOP) became effective on October 21, 2002, USDA's Agricultural Marketing Service (AMS) has published multiple rules amending the National List.

This proposed rule would amend the National List to reflect three recommendations submitted to the Secretary by the NOSB on October 25, 2019. This action would make the following changes to the National List based on the NOSB recommendations for three substances. Two substances are proposed to be added to the National List for use in organic crop production in response to petitions from the public. One substance is being recommended for removal from the National List because it is redundant to another listing on the National List. AMS published two notices in the Federal Register announcing the NOSB meetings and inviting public comments on the materials included in this proposed rule: November 26, 2018 (83 FR 60373) and May 22, 2019 (84 FR 23522). AMS also hosted public webinars (April 16 & 18, 2019, and October 15 & 17, 2019), to provide additional opportunities for public comment. The NOSB received additional comment during its public meetings on April 24 – 25, 2019,¹ and October 23 – 24, 2019.² Table 1 summarizes the proposed changes to the National List.

Table 1. Proposed Amendments to the National List.

¹ National Organic Standards Board (NOSB) Spring 2019 Meeting:

<https://www.ams.usda.gov/event/national-organic-standards-board-nosb-meeting-seattle-wa>

² National Organic Standards Board (NOSB) Fall 2019 Meeting: <https://www.ams.usda.gov/event/national-organic-standards-board-nosb-meeting-pittsburgh-pa>

Substance	National List Section	Proposed rule action
Potassium hypochlorite	§ 205.601	Add to National List
Fatty alcohols (C ₆ , C ₈ , C ₁₀ , C ₁₂)	§ 205.601	Add to National List
Dairy cultures	§ 205.605	Remove from National List

II. Overview of Proposed Amendments

The following provides an overview of the proposed amendments to designated sections of the National List regulations:

§ 205.601 Synthetic substances allowed for use in organic crop production

This proposed rule would add two substances to § 205.601, synthetic substances allowed for use in organic crop production.

Potassium hypochlorite

The proposed rule would amend the National List to add potassium hypochlorite to § 205.601(a) as a synthetic substance allowed for use as a pre-harvest sanitizer in irrigation water in organic crop production. Table 2 illustrates the proposed listing.

Table 2. Proposed amendment for potassium hypochlorite

Current rule:	N/A
Proposed amendment:	Add potassium hypochlorite to § 205.601(a)(2).

In November 2018, AMS received a petition to add potassium hypochlorite as a synthetic substance allowed for use in organic crop production.^{3, 4} The petition proposed to add potassium hypochlorite to § 205.601 as a type of chlorine material that can be used as a pre-harvest sanitizer.

³ The initial petition for potassium hypochlorite was submitted in November 2018:
<https://www.ams.usda.gov/sites/default/files/media/PotassiumHypochloritePetition.pdf>

⁴ A revised petition for potassium hypochlorite was submitted in March 2019:
<https://www.ams.usda.gov/sites/default/files/media/PotassiumHypochloriteRevisedPetition03262019.pdf>

After considering the petition, the 2011 technical report on chlorine materials, and the public comments, the NOSB determined that this use of potassium hypochlorite meets the OFPA criteria for allowed synthetic substances in organic crop production.⁵ The NOSB concluded that potassium hypochlorite is similar to other chlorine materials allowed in organic crop production and allowing its use supports compliance with the Food Safety and Modernization Act (FSMA) (21 U.S.C. 2201-2252) to sanitize irrigation water. In addition, the NOSB indicated that potassium hypochlorite has advantages over sodium hypochlorite, also an allowed chlorine material at § 205.601(a)(2)(iv), because potassium is a plant nutrient and is unlikely to increase soil salinization because it does not contain sodium.

The NOSB recommended adding potassium hypochlorite to § 205.601 as a synthetic substance allowed for use as a pre-harvest sanitizer for use in irrigation water in organic crop production. The recommendation also specified that the concentration of potassium hypochlorite in irrigation water should not exceed maximum residual disinfectant limits specified under the Safe Drinking Water Act (SDWA) (42 U.S.C. 300(f) et seq.).^{6, 7} Notably, the recommendation also explained the intent for a more limited allowance for potassium hypochlorite in comparison to other allowed chlorine substances on the National List for crop production. The recommendation specified that an allowance for potassium hypochlorite be limited to irrigation water. Additional uses, including post-harvest, would be prohibited.

⁵ Chlorine compounds technical report, 2011: <https://www.ams.usda.gov/sites/default/files/media/Chlorine%2020TR%202011.pdf>. This technical report describes the manufacture, industry uses, regulation, and chemical properties of chlorine compounds. Information in this technical report is transferable to potassium hypochlorite.

⁶ NOSB potassium hypochlorite recommendation: <https://www.ams.usda.gov/sites/default/files/media/CSPotassiumHypochlorite.pdf>

⁷ Safe Drinking Water Act (SDWA) <https://www.epa.gov/sdwa>

AMS concurs with the NOSB’s determination that potassium hypochlorite is a synthetic substance and that the use of potassium hypochlorite satisfies the OFPA criteria for allowed synthetic substances in organic crop production. Consistent with the NOSB recommendation, this proposed rule would amend the National List by adding potassium hypochlorite to the National List as a type of chlorine material that can be used as a pre-harvest sanitizer. Given that the NOSB recommendation specified that potassium hypochlorite be allowed for irrigation water only, we are proposing that potassium hypochlorite would not be allowed for organic edible sprout production. This would clarify how the allowance for potassium hypochlorite is different from other allowed chlorine materials which are permitted for use in organic edible sprout production.

Fatty alcohols (C₆, C₈, C₁₀, C₁₂)

The proposed rule would amend the National List to add fatty alcohols (C₆, C₈, C₁₀, C₁₂) to § 205.601 as a synthetic substance allowed for use in crop production. Table 3 illustrates the proposed listing.

Table 3. Proposed amendment for fatty alcohols (C₆, C₈, C₁₀, C₁₂)

Current rule:	N/A
Proposed amendment:	Add fatty alcohols (C ₆ , C ₈ , C ₁₀ , and/or C ₁₂) to § 205.601(k).

AMS received a petition to add fatty alcohols (C₆, C₈, C₁₀, C₁₂) to the National List for use in organic crop production.^{8,9} The petition identified the intended use as sucker control in tobacco production. The petition explained that sucker control in

⁸ Fatty alcohols petition, December 10, 2018:

<https://www.ams.usda.gov/sites/default/files/media/RevisedPetitionNaturalFattyAlcoholsforUseonOrganicTobaccoCrops.pdf>

⁹ In 2015, a petition was submitted for fatty alcohols octanol-decanol mix. The NOSB did not recommend listing this substance. The 2015 fatty alcohols petition and the corresponding 2017 NOSB recommendation are available in the list of petitioned substances on the AMS website: <https://www.ams.usda.gov/rules-regulations/organic/national-list/f>.

tobacco production improves yield and quality of the plant, reduces pest pressure and supports crop rotation practices.

After considering the petition, the technical report on fatty alcohols, and the public comments, the NOSB determined that this use of fatty alcohols meets the OFPA criteria for allowed synthetic substances in organic tobacco production.¹⁰ The NOSB concluded that the alternative materials for sucker control are ineffective and that fatty alcohols used for sucker control are essential for organic tobacco production. Further, the NOSB also cited human health issues from manual desuckering which can cause nicotine poisoning and other health issues in workers due to heavy exposure to the nicotine present in the tobacco plant through dermal (skin) exposure. Consequently, the NOSB recommended the addition of fatty alcohols (C₆, C₈, C₁₀, C₁₂) to the National List for organic tobacco production.¹¹

AMS concurs with the NOSB's determination that fatty alcohols are a synthetic substance and that the use of fatty alcohols satisfies the OFPA criteria for allowed synthetic substances. Some discussion opined that the use of fatty alcohols for desuckering is primarily for economic benefit and that manual desuckering of tobacco plants, while more expensive, is the only method compatible with organic production. AMS is not persuaded by that argument because manual desuckering may pose adverse health risks to workers due to contact with tobacco plants. There are no alternative practices or allowed materials under current USDA organic regulations that perform this function. Therefore, AMS concurs that this substance is necessary for organic tobacco production and is consistent with organic farming. This proposed rule would amend the

¹⁰ Fatty alcohols technical report, 2016:
<https://www.ams.usda.gov/sites/default/files/media/FattyAlcohols020217.pdf>.

¹¹ NOSB recommendation for fatty alcohols, October 2019:
https://www.ams.usda.gov/sites/default/files/media/CSFattyAlcoholsFinalRec_0.pdf.

National List by adding fatty alcohols (C₆, C₈, C₁₀, and/or C₁₂) for sucker control in organic tobacco production.

The parenthetical content (C₆, C₈, C₁₀, and/or C₁₂) for the proposed listing specifies the range of alcohols that would be included in this listing. AMS is proposing that fatty alcohol products allowed for sucker control in organic production may contain either some or all of these fatty alcohols. NOP understands that referring to the carbon chain length of fatty alcohols are commonly understood by industry and regulation. In listing “C₆, C₈, C₁₀, and/or C₁₂” as allowed fatty alcohols, it should be understood that these carbon chain designations refer to 1-hexanol, 1-octanol, 1-decanol, and 1-dodecanol. AMS welcomes comments on whether the proposed listing provides the clarity for material reviewers to clearly determine which products would be permitted for sucker control in organic tobacco production.

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

This proposed rule would remove one substance from § 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

Dairy Cultures

The proposed rule would amend the National List by removing dairy cultures as a nonsynthetic nonagricultural substance listed in § 205.605(a) for use in organic handling. The NOSB recommended removing dairy cultures from the National List because dairy cultures are allowed under the listing for “microorganisms” in § 205.605.¹² The NOSB

¹² The NOSB recommended the removal of dairy cultures from the National List as part of its 2021 sunset review. The OFPA sunset provision (7 U.S.C. 6517(e)) requires the NOSB to review exemptions or prohibitions to the National List within 5 years of such exemption or prohibition being adopted or

determined that dairy cultures is a redundant listing and that removing dairy cultures would have no negative impacts because these ingredients would continue to be allowed in organic handling. In addition, the NOSB indicated that permitted ancillary substances in dairy cultures would continue to be allowed under the “microorganisms” listing.

AMS concurs that microorganisms are inclusive of dairy cultures and that listing both dairy cultures and microorganisms on the National List is redundant. AMS’ intent and belief are that current use patterns for approved dairy cultures would not be affected by the changes included in this proposed rule. Therefore, AMS is proposing to remove dairy cultures from the National List.

III. Related Documents

AMS published two notices in the Federal Register announcing the April 2019 and October 2019 NOSB meetings: November 26, 2018 (83 FR 60373) and May 22, 2019 (84 FR 23522). At these meetings, the NOSB deliberated on substances petitioned as amendments to the National List and substances under sunset review.

IV. Statutory and Regulatory Authority

The OFPA authorizes the Secretary to make amendments to the National List based on recommendations developed by the NOSB. Sections 6518(k) and 6518(n) of the OFPA authorize the NOSB to develop recommendations for submission to the Secretary to amend the National List and to establish a process by which persons may petition the NOSB for the purpose of having substances evaluated for inclusion on or deletion from the National List. Section 205.607 of the USDA organic regulations permits any person to petition to add or remove a substance from the National List and

reviewed. The NOSB subsequently votes to remove a substance allowance or prohibition from the National List. The NOSB recommendation to remove dairy cultures is available here: <https://www.ams.usda.gov/sites/default/files/media/HS2021SunsetReviews.pdf>.

directs petitioners to obtain the petition procedures from USDA. The current petition procedures published in the Federal Register (81 FR 12680, March 10, 2016) for amending the National List can be accessed through the NOP Program Handbook on the NOP Web site at <https://www.ams.usda.gov/rules-regulations/organic/handbook>.

A. Executive Orders 12866 and Regulatory Flexibility Act

This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) has exempted from Executive Order 12866.

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to the action. Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

The Small Business Administration (SBA) sets size criteria for each industry described in the North American Industry Classification System (NAICS) to delineate which operations qualify as small businesses.¹³ The SBA has classified small agricultural producers that engage in crop and animal production as those with average annual receipts of less than \$1,000,000. Handlers are involved in a broad spectrum of food production activities and fall into various categories in the NAICS Food Manufacturing sector. The small business thresholds for food manufacturing operations are based on the number of employees and range from 500 to 1,250 employees, depending on the specific

¹³ Table of Small Business Size Standards Matched to North American Industrial Classification System Codes, August 19, 2019: https://www.naics.com/wp-content/uploads/2017/10/SBA_Size_Standards_Table.pdf

type of manufacturing. Certifying agents fall under the NAICS subsector, “All other professional, scientific and technical services.” For this category, the small business threshold is average annual receipts of less than \$16.5 million.

AMS has considered the economic impact of this proposed rulemaking on small agricultural entities. Data collected by the USDA National Agricultural Statistics Service and the NOP indicate most of the certified organic production operations in the United States would be considered small entities. According to the 2019 Certified Organic Survey, 16,524 organic farms in the United States reported sales of organic products and total farmgate sales in excess of \$9.9 billion.¹⁴ Based on that data, organic sales average \$601,000 per farm. Assuming a normal distribution of producers, we expect that most of these producers would fall under the \$1,000,000 sales threshold to qualify as a small business.

According to the NOP’s Organic Integrity Database, there are 19,832 organic handlers that are certified under the USDA organic regulations, of which 10,500 are based in the U.S.¹⁵ The Organic Trade Association’s 2020 Organic Industry Survey¹⁶ has information about employment trends among organic manufacturers. The reported data are stratified into three groups by the number of employees per company: less than 5; 5 to 49; and 50 plus. These data are representative of the organic manufacturing sector and the lower bound (50) of the range for the larger manufacturers is significantly smaller than the SBA’s small business thresholds (500 to 1,250). Therefore, AMS expects that most organic handlers would qualify as small businesses.

¹⁴ U.S. Department of Agriculture, National Agricultural Statistics Service. 2019 Organic Survey. https://www.nass.usda.gov/Publications/AgCensus/2017/Full_Report/Volume_1,_Chapter_1_US/. The number of organic farms includes only certified farms.

¹⁵ Organic Integrity Database: <https://organic.ams.usda.gov/Integrity/>. Accessed on August 18, 2020.

¹⁶ 2020 Organic Industry Survey, Organic Trade Association. Available for purchase at <https://ota.com/organic-market-overview/organic-industry-survey>.

The USDA has 77 accredited certifying agents who provide organic certification services to producers and handlers. The certifying agent that reports the most certified operations, nearly 3,500, would need to charge approximately \$4,200 in certification fees in order to exceed the SBA's small business threshold of \$16.5 million. The costs for certification generally range from \$500 to \$3,500, depending on the complexity of the operation. Therefore, AMS expects that most of the accredited certifying agents would qualify as small entities under the SBA criteria.

The economic impact on entities affected by this rule would not be significant. The effect of this rule, if implemented as final, would be to allow the use of two additional substances in organic crop production and remove one redundant listing from the regulations. Adding two substances to the National List would increase regulatory flexibility and would give small entities more tools to use in day-to-day operations. This action would also remove dairy cultures as a redundant listing and would have no impact on the industry. AMS reviewed comments submitted to the NOSB regarding the materials petitioned for inclusion on and recommended for removal from the National List. Therefore, AMS concludes that the economic impact of this addition, if any, would be minimal. Accordingly, USDA certifies that this rule would not have a significant economic impact on a substantial number of small entities.

B. Executive Order 12988.

Executive Order 12988 instructs each executive agency to adhere to certain requirements in the development of new and revised regulations in order to avoid unduly burdening the court system. This proposed rule is not intended to have a retroactive effect. Accordingly, to prevent duplicative regulation, states and local jurisdictions are preempted under the OFPA from creating programs of accreditation for private persons or state officials who want to become certifying agents of organic farms or handling operations. A governing state official would have to apply to USDA to be accredited as a

certifying agent, as described in section 6514(b) of the OFPA. States are also preempted under sections 6503 through 6507 of the OFPA from creating certification programs to certify organic farms or handling operations unless the state programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to section 6507(b)(2) of the OFPA, a state organic certification program that has been approved by the Secretary may, under certain circumstances, contain additional requirements for the production and handling of agricultural products organically produced in the state and for the certification of organic farm and handling operations located within the state. Such additional requirements must (a) further the purposes of the OFPA, (b) not be inconsistent with the OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

In addition, pursuant to section 6519(c)(6) of the OFPA, this proposed rule would not supersede or alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601–624), the Poultry Products Inspection Act (21 U.S.C. 451–471), or the Egg Products Inspection Act (21 U.S.C. 1031–1056), concerning meat, poultry, and egg products, respectively, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et seq.*), nor the authority of the Administrator of the Environmental Protection Agency under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 *et seq.*).

C. Paperwork Reduction Act.

No additional collection or recordkeeping requirements are imposed on the public by this proposed rule. Accordingly, OMB clearance is not required by the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, Chapter 35.

D. Executive Order 13175

This proposed rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on tribal governments and will not have significant tribal implications.

F. General Notice of Public Rulemaking.

This proposed rule reflects recommendations submitted by the NOSB to the Secretary to add two substances to the National List and to remove one substance from the National List. A 60-day period for interested persons to comment on this rule is provided.

List of Subjects in 7 CFR Part 205

Administrative practice and procedure, Agriculture, Archives and records, Crops, Imports, Labeling, National list, National Organic Standards Board (NOSB), Organically produced products, Plants, Reporting and recordkeeping requirements, Seals and insignia, Soil conservation, Sunset.

For the reasons set forth in the preamble, AMS proposes to amend 7 CFR part 205 as follows:

PART 205—NATIONAL ORGANIC PROGRAM

1. The authority citation for 7 CFR part 205 is revised to read as follows:

Authority: 7 U.S.C. 6501–6524.

2. Amend § 205.601 by:

- a. Revising paragraph (a)(2)(iv);
- b. Adding paragraph (a)(2)(v); and
- c. Revising paragraph (k).

The revisions and addition to read as follows:

§ 205.601 Synthetic substances allowed for use in organic crop production.

* * * * *

(a) * * *

(2) * * *

(iv) Potassium hypochlorite—not allowed for edible sprout production.

(v) Sodium hypochlorite.

* * * * *

(k) As plant growth regulators.

(1) Ethylene gas—for regulation of pineapple flowering.

(2) Fatty alcohols (C₆, C₈, C₁₀, and/or C₁₂)—for sucker control in organic tobacco production.

* * * * *

§ 205.605 [Amended]

3. In § 205.605, amend paragraph (a) by removing the words “Dairy cultures”.

Bruce Summers, Administrator,
Agricultural Marketing Service.